K043179

FEB - 7 2005

# 510(k) SUMMARY
OCTOBER 18, 2004

In accordance with the Safe Medical Device Act (SMDA) and in conformance with 21 CFR 807.87, R&R Medical, Inc., hereby submits this request and accompanying information for review of our Pre-market Notification 510(k) documentation. R&R Medical intends to produce and introduce into interstate commerce for commercial distribution the Stealth Fusion Fixation System.

I. SUBMITTER/AUTHORIZED REPRESENTATIVE

Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, TX 78681
Tele/Fax: 512-388-0199
Ortho.medix@sbcglobal.net

II. CLASSIFICATION NAME

Single/multiple component metallic bone fixation appliances and accessories

III. COMMON NAME

External Bone Fixation device

IV. DEVICE TRADE NAME

Stealth Fusion System

V. CLASSIFICATION

a. Class: Per 21 CFR Sec 888.3030
b. Device Panel Code: Orthopedics/87
c. Device Product Code: KTT, JDW

VI. PREDICATE DEVICES

a. Ilizarov External Fixation System (Smith-Nephew Richards)
b. Orthofix® Modulsystem

VII. DESCRIPTION

The Stealth Fusion System is an orthopedic device indicated for the use of bone fusion and other bone abnormalities and deformities. As with most external fixation devices, the standard Stealth Fusion System fixator assembly consists of three basic types of elements: 1) bone anchorage elements, 2) bridge elements, and 3) connection elements. The Stealth Fusion System design allows freedom of pin placement, ease of assembly and stable fixation of bone fragments with the possibility of axial loading of the lower extremity and immediate range of motion of all adjacent joints.

VIII. INTENDED USE

The Stealth Fusion System and its accessory components are intended to be used on adults or pediatric patients as required and are intended to be used for ankle and foot joints fusion; to stabilize fractures of the foot bones; (open and closed); post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union of foot bones; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue foot defects; joint arthrodesis; and management of comminuted intra-articular foot bone fractures.

IX. TECHNOLOGICAL CHARACTERISTICS

The principle of operation of the Stealth Fusion System is the same as that of its predicate devices. The intended use is very similar to the predicate devices. That is, it is used as an external multilateral bone fixation system. The materials used in this device is the same or similar to those used in the predicate device.

X. SUBSTANTIAL EQUIVALENCE INFORMATION

The Stealth Fusion System and its accessory components, like the Ilizarov and the Orthofix® Modulsystem, is intended to be used on adults or pediatric patients as required and is intended to be used for ankle and foot joints fusion; to stabilize fractures of the foot bones. The clinical function and design is very similar to that of the predicate devices. The fixator pins are manufactured from the same medical grade stainless steel. The external components are manufactured from the same aluminum alloy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2005

R & R Medical, Inc.
C/o Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K043174
Trade/Device Name: Stealth Fusion System
Regulation Numbers: 21 CFR 888.3030
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: KTT, JDW
Dated: October 18, 2004
Received: November 16, 2004

Dear Mr. J.D. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

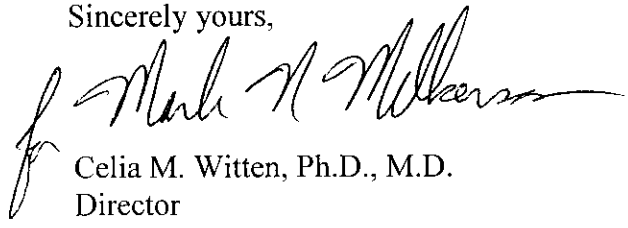
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division Of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) number (if known): K043174 ~~Not yet determined~~

Device Name: **Stealth Fusion System**

Indications for Use:

The Stealth Fusion System and its accessory components are intended to be used on adults or pediatric patients as required and are intended to be used for ankle and foot joints fusion; to stabilize fractures of foot bones; (open and closed); post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union of foot bones; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue foot defects; joint arthrodesis; and management of comminuted intra-articular foot bone fractures.

PRESCRIPTION USE X

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043174